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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/757,688

01/11/2001

Wolfgang Heil

PLOVIN-2A

7991

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7590

04/19/2006

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EXAMINER

CHANNAVAJALA, LAKSHMI SARADA

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/757,688	Applicant(s) HEIL ET AL.	
	Examiner Lakshmi S. Channavajjala	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 173-192, 195-230, 233 and 234 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 173-192, 195-230, 233 and 234 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11-18-05, 12-1-05, 2/10/06</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt of response dated 1-31-06, IDS dated 11-18-05, 12-01-05 and 2-10-05 is acknowledged.

Claims 173-192, 195-230, 233 and 234 are pending.

The following rejection of record has been maintained:

Double Patenting

Claims 173-192, 195-230, 233 and 234 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-49 of U.S. Patent No. 6,869,941. Although the conflicting claims are not identical, they are not patentably distinct from each other. Although the method of treating a disease, disorder or symptom issued in the above patent is broader in scope than the instant method claims, the issued claims are overlapping in scope with that of the instant claims because the dosage regimen of estrogen and drospirenone of the issued claims follow the same pattern as that of the instant regimen to achieve the claimed method. By definition, the effective amount of drospirenone for achieving the above regimen (and hence the method) of the issued claims involves micronized drospirenone having the same surface area and particle sizes as that of the instant claims and also has the same dissolution pattern as claimed in the instant application. Thus, the method of the patented as well as the instant claims involves the same composition and hence the instant method would have been obvious for one of an ordinary skill in the art at the time of the instant invention from the patented claims.

Response to Arguments

Applicant's arguments filed 1-31-06 have been fully considered but they are not persuasive.

Applicants traversed the above Double patenting rejection and state that the method claims 19-49 of the '941 patent recite use of drospirenone, in general as shown in claim 19, upon which all the other method claims ultimately depend. It is argued that the '941 claims do not recite a method using drospirenone "in a form having a rapid dissolution such that at least 70% of said drospirenone is dissolved from a tablet containing 3 mg of drospirenone in 900 ml of water at 37°C within 30 minutes, as determined by USP XX111 Paddle Method using a USP dissolution test apparatus 2 and 50 rpm as the stirring rate, "in a form having a surface area of more than 10 000 cm²/g " or "wherein the drospirenone has a particle size distribution such that not more than 2% of the particles have a diameter of more than 30 μm".

Applicants' arguments are not found persuasive because the instant method claims treat the same conditions as that of the patented claims and both sets of claims employ the same active agents i.e., drospirenone and estrogen combination. Further, the dosage regimen of estrogen and drospirenone of the issued claims follow the same pattern as that of the instant regimen to achieve the claimed method. While the patented claims fail to recite the claimed limitations of dissolution rate, surface area and particle size distribution, the patented claims require sufficient amount of drospirenone and estrogen to achieve an effective treatment of a disease or a disorder or a symptom associated with a deficient endogenous level of estrogen in a woman. A sufficient

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amount of drospirenone by definition involves micronized drospirenone having the same surface area and particle sizes and also has the same dissolution pattern as claimed in the instant application. Therefore, even though the patented claims fail to recite the above argued parameters; the patented claims still achieve an effective treatment with sufficient amount of drospirenone and estrogen, which is achieved by definition with a drospirenone possessing the above characteristics. Accordingly, the instant claimed method of treatment would have been obvious over the patented method.

Regarding the inquiry in the Office Action as to common ownership, applicants state that the inventions of this application and U.S. Patent No. 6,869,941 were commonly owned or subject to an obligation of common assignment at the time of the invention of this application and therefore the rejection of claims 173-192, 195-230, 233 and 234 as directed to an invention not patentably distinct from claims 19-49 of commonly assigned 6,869,941 has been withdrawn.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
Art Unit 1615
April 14, 2006